

REMARKS

The pending claims, 1-52, are subject to a restriction requirement in which the claims were assigned to nine different groups. With respect to Groups I and II, Applicants submit that this Requirement is in error and that these groups should be rejoined.

Request for Reconsideration

Applicants request reconsideration of the restriction requirement insofar as both Group I (claims 1-12) and Group II (claims 13-18) are directed to methods of identifying a mammal having, or at increased risk of acquiring, a proliferative disease and insofar as these methods are based on the same underlying defect in the mammal, a proliferative disease-associated alteration in a *Sal2* sequence. The Office distinguishes the two restriction groups based on the statement that "claims 1-12 are drawn to a method comprising the step of determining whether there is a proliferative disease-associated alteration in a *Sal2* nucleic acid in a mammal" and that "claims 13-18 are drawn to a method comprising the step of determining whether there is a proliferative disease-associated alteration in a *Sal2* protein in a mammal" (emphasis added). Nonetheless, Applicants submit that these claims are directed to the same invention.

The invention to which claims 1-52 are directed involves identifying the presence of a proliferative disease-associated alteration in a *Sal2* sequence in a mammal.

Applicants submit that, once a proliferative disease-associated alteration has been identified in a *Sal2* sequence, one skilled in the art would know how to assay for the presence of this alteration in a mammal, not only in a *Sal2* nucleic acid sequence, but also in a *Sal2* protein sequence encoded by an altered *Sal2* nucleic acid sequence, using a variety of assays. In addition, the assays involved in identifying alterations in nucleic acid or amino acid sequences are standard in the art and examples of such assays are provided throughout Applicants' specification, for example, at page 19, lines 8-24, page 36, line 29, to page 37, line 14, page 39, lines 1-24, and page 42, lines 17-28. In view of these arguments, Applicants submit that the methods of claims 1-12 and 13-18 are simply different embodiments of the same invention.

The methods are not independent and distinct as both the *Sal2* nucleic acid and the *Sal2* protein sequence are altered in a proliferative disease-associated alteration in a *Sal2* sequence. For example, a change in a *Sal2* protein sequence indicates an alteration in the *Sal2* nucleic acid sequence encoding this protein and, similarly, a change in a *Sal2* nucleic acid sequence that is associated with a proliferative disease will result in a change in the *Sal2* protein sequence that it encodes if this mutation alters a codon encoding an amino acid. Moreover, this exact situation is exemplified in Applicants' specification, for instance, at page 36, lines 11-28.

Applicants submit that the proposed limitation, which looks at changes in a *Sal2* nucleic acid sequence, or to looking at changes in a *Sal2* protein sequence unduly narrows the

scope of the invention. For example, if the invention were to be limited to identifying whether a mammal has an alteration in a *Sal2* nucleic acid sequence, a potential infringer may simply elect to look at a Sal2 protein (e.g., one encoded by the altered *Sal2* nucleic acid sequence) in this mammal, using nothing more than standard methods, to avoid infringement despite the fact that the same underlying alteration in a Sal2 sequence is assayed in both cases.

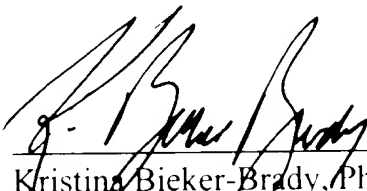
In sum, based on the above arguments, Groups I and II should be rejoined as being drawn to the same invention. Applicants request reconsideration on this issue and request examination of Groups I and II in this application.

Enclosed is a petition to extend the period for replying for one month, to and including May 13, 2002. If there are any other charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date:

May 8, 2002



Kristina Bieker-Brady, Ph.D.
Reg. No. 39,109

Clark & Elbing LLP
101 Federal Street
Boston, MA 02111
Telephone: 617-428-0200
Facsimile: 617-428-7045
00742 066001 Reply to Restriction Requirement.wpd



21559

PATENT TRADEMARK OFFICE